Page 16, lines 24 to 27:

> ... the formed membrane is removed from the mold after **soaking** for a short period (hours) in a sterile buffered solution (*e.g.*, Hank's balanced salt solution or HBSS) at room temperature. [Emphasis added.]

Page 17, lines 29 to 31:

> Each membrane is removed from the mold after **soaking** in a serile buffered solution (*e.g.*, HBSS) at room temperature. [Emphasis added.]

Page 18, lines 1 to 4:

> ... The sterile membranes can be **soaked** in HBSS containing glycine (5% in HBSS) to remove residual unreactive crosslinking agent. Membranes are further rinsed in HBBS (at least 3 times). [Emphasis added.]

The plain dictionary meaning of "soaked" is to make thoroughly wet or **saturated** by placing in liquid.

Support for **"homopolymer"** may be found throughout the specification, and in particular at:

Page 14, lines 15 to 20:

> ... and the polyacrylamide is **pNIPAAm** provided in a solution of about 2-10%, in a further embodiment, about 4% in water. [Emphasis added.]

Page 16, Example 1, lines 10 to 12:

> A 4% (w/v) solution of **pNIPAAm homopolymer** is made in water (ddH_2O) and sterilized by autoclaving or by filtering (0.24tm). [Emphasis added.]

Page 17, Example 3, lines 16 to 17:

> A sterile RTT collagen viscous solution and a 1% (w/v) solution of **pNIPAAm** are made **as described in Example 1.** [Emphasis added.]

Page 20, lines 4 to 5:

> ... The membranes result from the mixture of collagen and **pNIPAAm**. [Emphasis added.]

Polymers that contain only a single type of monomer are known as homopolymers, while polymers containing a mixture of monomers are known as copolymers. Based on the specification as a whole, a person of skill in the art would understand that **"pNIPAAm"** is a **"homopolymer"**.

Paragraph 1(b)

The Examiner asserts that claim 1 appears to be contradictory given that the membrane is defined as "saturated with a hydrating solution" but at the same time it consists essentially of "a dried solution of a mixture of a biological polymer and a polyacrylamide homopolymer". The Examiner further asserts that he was not able to find the combined limitations in the specification as originally filed.

Amended **claim 1** reads as follows:

> A corneal implant for improving or correcting vision comprising a membrane[[,]] saturated with a hydrating solution, said membrane ~~formed from a solution of~~ consisting essentially of a dried solution of a mixture of a biological polymer ~~mixed with~~ and a polyacrylamide homopolymer[[,]] ~~wherein said solution has been dried to form a membrane and the membrane has been hydrated for use as a corneal implant~~.

MPEP §2111 (Claim Interpretation; Broadest Reasonable Interpretation) provides that:

> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004).

MPEP §1504.04 (Considerations Under 35 U.S.C. 112) further provides that:

> "[T]he definiteness of the language employed must be analyzed - not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

Support for "dried solution" may be found throughout the specification, and in particular at:

Page 7, lines 1 to 8:

> The invention further relates to a method for preparing the above-mentioned corneal implant, the method comprising: (a) providing a polymer mixture solution comprising a biological polymer and a polyacrylamide (*e.g.* a solution obtained by combining a biological polymer and a polyacrylamide); (b) transferring the solution onto a drying surface; (c) allowing the solution to dry to obtain a membrane for use in the corneal implant.

Support for "saturated with a hydrating solution" may be found throughout the specification, and in particular at:

Page 16, lines 24 to 27:

> ... the formed membrane is removed from the mold after **soaking** for a short period (hours) in a sterile buffered solution (*e.g.*, Hank's balanced salt solution or HBSS) at room temperature. [Emphasis added.]

Page 17, lines 29 to 31:

> Each membrane is removed from the mold after **soaking** in a serile buffered solution (*e.g.*, HBSS) at room temperature. [Emphasis added.]

Page 18, lines 1 to 4:

> ... The sterile membranes can be **soaked** in HBSS containing glycine (5% in HBSS) to remove residual unreactive crosslinking agent. Membranes are further rinsed in HBBS (at least 3 times). [Emphasis added.]

See also page 7, lines 16 to 18, page 14, lines 11 to 15 and page 16, lines 19 to 24.

It should therefore be clear that the claimed corneal implant comprises (1) a membrane saturated with a hydrating solution, and that (2) the membrane consists essentially of a dried solution of a mixture of a biological polymer and a polyacrylamide homopolymer. In other words, the solution of the mixture of the biological polymer and the polyacrylamide homopolymer is dried to form a membrane which is then rehydrated with a solution.

Further, in Applicant's letter of January 18, 2008, support for the claim amendments was identified in the specification as originally filed, for example, at:

Page 13, lines 21 to 22	The physical properties of the membrane may be modified for example as a function of *rehydration*, or via the presence of lipids and/or proteins.
Page 14, lines 3 to 10	The membrane of the invention may further comprise/have associated with it various compounds e.g. drugs, biological materials (e.g. peptides/proteins, lipids, etc.), crosslinkers, plasticizers, cytokines, etc. to fulfill or further contribute to an aspect of the desired functionality of the corneal implant in any particular situation. Such agents or compounds may be introduced during the making of the membranes or *after their formation.* [Emphasis added.]
Page 19, Example 5	A variety of agents or compounds (e.g., crosslinking, plasticizer, drugs, cytokines) can be introduced during the making of the membranes from examples I to IV. Compounds can be introduced either during the mixing of both collagen and pNIPAAm *or after the formation of a membrane. The latter can be dried, thereby, the agents can be introduced during the rehydration process.* Otherwise, the agents can be introduced on the rehydrated membrane. [Emphasis added.]
Page 20, lines 11 to 13	Albumax (a lipid rich bovine serum albumin, ...) *can be added during rehydration* with Hank's balanced salt solution (HBSS). [Emphasis added.]

Also, as stated previously in Applicant's letter, drying of the mixed polymer solution produces an interpenetrating hydrogel network, which strengthens and stabilizes the formed membrane **without any chemical bonds. Saturation** of the dried membrane with a hydrating solution alters its physical properties centrally required for functionality (*e.g.* optical clarity), pliability (*e.g.* easy for the surgeon to manipulate/handle) and wearability (*e.g.* wettable) as a corneal implant.

Accordingly, Applicant submits that the claim language is not contradictory and clearly defines the invention consistent with the teaching and examples provided in the specification.

In view of the foregoing, early favourable consideration of this application is earnestly solicited. It is believed this responds to all of the Examiner's concerns. However if the Examiner believes that the claims do not overcome any of the rejections and/or does not consider that the application is in a form for allowance, then he is requested to contact, Elizabeth A. Hayes-Quebec (Reg. No. 48,305) at 613-232-2486 to discuss the matter.

Respectfully submitted,

CHARLES J. DOILLON, ET AL

By _____

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